



UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/882,431	06/25/97	ULRICH	R 003/037/SAP

KM

HM12/0425
MCMR JA JOHN MORAN
U S ARMY MEDICAL RESEARCH & MATERIEL COM
504 SCOTT STREET
FORT DETRICK MD 21702-5012

EXAMINER

ALLEN, M

ART UNIT	PAPER NUMBER
----------	--------------

1631

DATE MAILED: 04/25/01

24

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

08/882,431

Applicant(s)

ULRICH ET AL.

Examiner

Marianne Allen

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 January 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-6,12-14,18,21-23,29-31,37-39,43,44,47-49,53,56-58,62 and 65-67. is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

Non-elected claims 2-3, 7-11, 15-17, 19-20, 24-28, 32-36, 40-42, 45-46, 50-52, 54-55, 59-61, 63-64, 68-70, and 100-109 have been cancelled.

Response to Arguments

Applicant's arguments filed 1/23/01 have been fully considered but they are not persuasive. Applicant is advised that the header information on their response lists the wrong serial number (09/882,431 rather than 08/882,431) which has delayed matching the papers with the correct file.

Claims 1, 4-6, 12-14, 18, 21-23, 29-31, 37-39, 43-44, 47-49, 53, 56-58, 62, and 65-67 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

This rejection is maintained for reasons of record and as reiterated below. Claim 1 has been amended to refer to multiple subsets of T cells with basis given as Examples 4, 8, and 9. Those examples referring to particular constructs of SEA are not germane for support of a generic concept with respect to SEB. Furthermore, particular constructs with these properties cannot be viewed as basis to support a generic claim to any SEB superantigen toxin encompassed by the claims. It is unclear if any of the exemplified and particularly claimed SEB mutants exhibit this property. Clarification is again requested with respect to the particularly claimed SEB mutants. Note that the discussion of SEB Y61A in the response is not one of the

Art Unit: 1631

particularly claimed embodiments. It is noted that it cannot be determined whether the claims to particular constructs are properly dependent upon claim 1 in the absence of this information. It is maintained that a fair reading of the specification would not convey to one of ordinary skill in the art that a generic class of SEB superantigen vaccines with these particular properties was contemplated as the invention. Applicant is again requested to point to particular basis in the specification by page and line number to support this **generic** concept. All of applicant's arguments are directed to particular examples and not to the generic concept now claimed.

Claim Rejections - 35 USC § 102

Claims 1, 18, 43-44, 53, and 62 are rejected under 35 U.S.C. 102(b) as being anticipated by Hayball et al. (International Immunology, 1994).

This rejection is reintroduced in view of applicant's arguments in the response that SEB Y61A possesses the properties recited in claim 1. Hayball et al. discloses a recombinantly produced SEB mutant with the same mutation. See abstract, methods at page 200, and Table 1.) Thus, the mutant of Hayball et al. would inherently possess these properties.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1631

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen, whose telephone number is (703) 308-0666. The examiner can normally be reached on Monday-Friday from 9:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028. Official FAX communications may be directed to either (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Marianne P. Allen
MARIANNE P. ALLEN
PRIMARY EXAMINER
~~GROUP 1800~~
AU 1631

Continuation of Disposition of Claims: Claims pending in the application are 1,4-6,12-14,18,21-23,29-31,37-39,43,44,47-49,53,56-58,62 and 65-67.